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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,935	05/09/2006	Robert S. Salter	0656-032US3A	5152

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EXAMINER
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GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1657

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01/28/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/578,935	<b>Applicant(s)</b> SALTER ET AL.	
	<b>Examiner</b> Ralph Gitomer	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 23-66 is/are pending in the application.
- 4a) Of the above claim(s) 38-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 23-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

The amendment received 11/13/08 has been entered and claims 1-17, 23-37 are considered here. Note that claim 13 is marked as original but has been amended. The amended title and abstract are acceptable.

Although not claimed, a reading of the specification reveals the point of novelty may reside in detecting antibiotics in a sample where different antibiotics to be detected have different thresholds of activity, so one can selectively reduce the sensitivity to one or more antibiotics to adjust the sensitivity of the assay to specific antibiotics and not to others. Some of the presently claimed features are directed to pH either directly or indirectly by claiming the buffers.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 1-2, 6-7, 9-12, 24-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Langeveld.

Langeveld (6,867,015) entitled "Rapid Microbiological Test for the Detection of Antibacterial Compounds" teaches in column 5 lines 5-36, the sensitivity of the test organism to specific antibiotics is adjustable by adding certain substances to the culture, changing the test conditions such as the pH or concentration of buffering substances or altering various ratios of components to increase or decrease the sensitivity. Substances that may be added include cysteine for example to diminish the sensitivity to penicillins.

All the features of the claims are taught by Langeveld for the same function as claimed.

Applicant's arguments filed 11/13/08 have been fully considered but they are not persuasive.

Applicants response argues that Langeveld does not suggest that the substance used to adjust the test sensitivity can be derived from the species used as the test organisms or a different microbial species with sensitivity to the antibiotic to be detected.

It is the examiner's position that Langeveld teaches cysteine as an example of a substance to adjust the sensitivity to the antibiotic and cysteine can be derived or extracted from most microbes. Note that when determining MIC of an antibiotic, the antibiotic is diluted with an aqueous solution to different concentrations and water can be derived or extracted from microbes.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-5, 8, 13-17, 23, 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langeveld.

See the teachings of Langeveld above.

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Claims 3-5, 8, 30-37 differ from Langeveld in that they specify the buffers and pH of the culture. Claims 13-17, 23 contain limitations directed to the inhibition reducing substance.

It would have been obvious to one of ordinary skill in the art at the time of the invention to select buffers and pH ranges because adjusting such basic parameters in culturing are standard practice to optimize growth. No function of any of the buffers or pH ranges are claimed.

In view of the teachings of Langeveld directed to selectively reducing the activity of antibiotics by adding a substance known to inhibit the desired antibiotic, adding an antibody, some binder, a protein, a receptor, a competitor or any such known inhibitor of an antibiotic for its known function with the expected result would have been obvious. All of the broadly claimed substances are known to inhibit antibiotics.

Applicant's arguments filed 11/13/08 have been fully considered but they are not persuasive.

See the discussions above.

Claims 1-13, 23-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific substances to selectively inhibit antibiotics, does not reasonably provide enablement for anything which may inhibit any antibiotic. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 1 the terms "a substance that reduces the culture growth inhibition of the antibiotic" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such substance would work in the instant invention.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative substances claimed.
2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related substances are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of substances.

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8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Applicant's arguments filed 11/13/08 have been fully considered but they are not persuasive.

Applicants response argues that the amendment to the claims of the substance is derived from the bacteria.

It is the examiner's position that there are many substances that can be derived from bacteria from carbon dioxide, oxygen, to water what will adjust the sensitivity to antibiotics. As claimed, one of skill in this art would not know what substances would be encompassed by the claims as presented.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Claim 2 is confusing regarding what extract is added to the culture.



Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/  
Primary Examiner, Art Unit 1657

Ralph Gitomer  
Primary Examiner  
Art Unit 1657